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K063468

APR 18 2007

**Medisurg Ltd.**  
100 West Fornance St.  
Norristown, PA 19401  
Phone (610) 277-3937 Fax (610) 277-7256

**Pre-market Notification [510(k)] Summary**

Submitters name: Richard J Fugo M.D., Ph.D.  
Contact person: Richard J Fugo M.D., Ph.D.

Date: October 30, 2006

Names: (807.92(a)(2))

- B) Classification name: Unit, electrosurgical, and accessories, dental
- C) Common/ usual name: The Fugo Blade for Dentistry
- D) Proprietary name: The Fugo Blade

Equivalence predicate device: (807.92(a)(3))

- A) Equivalence from an intended use standpoint: FDA cleared Wallach Quantum 500 electrosurgical generator for surgery – K000768
- B) Equivalence from a technologic standpoint:
  - a. Fugo Blade for Capsulotomy - FDA # K001498
  - b. Fugo Blade for Glaucoma – FDA # K041019
  - c. Fugo Blade for Peripheral Iridotomy – FDA # K050933

Description of the device (807.92(a)(4))

The Fugo Blade for dentistry is an electrosurgical device that is powered by the electromagnetic (EM) energy from flashlight size batteries. This energy is conditioned, tuned ( $9.8 \pm 2.0 \times 10^6$  Hz) and focused on a thin blunt cutting filament. Moreover, the EM energy from flashlight size (C cell) batteries is fed into a proprietary electronic network system which is activated by the surgeon with an on/off switch. This electronic system is fed EM energy from the battery energy supply source, then conditions it in a proprietary fashion and transfers it to the surgeon cutting filament. This

column of EM energy is capable of reacting with tissue. This column of EM energy causes the molecular bonds in the tissue which come in contact with the EM field to ionize and thereby break apart, a condition that plasma physicists refer to as "plasma formation". In this way, the molecular lattice of the tissue is broken into micro-fragments, thereby creating an incision, excision, ablation, vaporization, and hemostasis of oral soft tissue. This process was evaluated extensively in the FDA 510K submission K050933: The Fugo Blade for Peripheral Iridotomy.

#### Intended use of device (807.92(a)(5))

The Fugo Blade system is intended for incision, excision, ablation, vaporization and hemostasis of oral soft tissue e.g. excisional and incisional biopsies; exposure of unerupted teeth; fibroma removal; frenectomy and frenotomy; gingival troughing for crown impressions; gingivoplasty; gingivectomy; gingival incision and excision; hemostasis; implant recovery; incision and drainage of abscess; leukoplakia; operculectomy; oral papillectomies; pulpotomy; pulpotomy as an adjunct to root canal therapy; reduction of gingival hypertrophy; soft tissue crown lengthening; secular debridement; treatment of aphthous ulcers; vestibuloplasty; biopsy incision and excision; and lesion (tumor) removal.

#### Summary of technological characteristics (807.92(a)(6))

The Fugo Blade for Dentistry: Electromagnetic (EM) energy from flashlight size ("C" cell ) batteries is fed into a proprietary network system. This electronic system takes EM energy from the batteries then conditions, tunes ( $9.8 \pm 2.0 \times 10^6$  Hz) and focuses this EM energy around an incising probe at the end of the Fugo Blade electrosurgical hand piece. This column of EM energy is capable of reacting with tissue in an intended path of incision. This reaction causes the molecular bonds in the tissues which come in contact with the Fugo Blade to absorb the Fugo Blade EM energy and thereby have the molecular bonds shatter. Upon shattering, the molecules ionize and create a substance that physicists refer to as a "plasma field". In this way, the molecular lattice of the tissue is broken down, thereby creating an incision, excision, ablation, vaporization as well as hemostasis of oral soft tissue. The plasma field generation can easily be visualized under a microscope. Such images have been published by Medisurg Ltd. in scientific journals and advertisements. This Fugo Blade plasma cloud has been studied and analyzed by the Plasma Lab at Swarthmore College, Swarthmore, PA. The issue of Fugo Blade field generation was addressed and evaluated in the

FDA 510K submission # K050933 "The Fugo Blade for Peripheral Iridotomy".

Non-clinical performance data (807.92(b)(1))

The Fugo Blade uses 7.2 V batteries to focus an electromagnetic field into tissue in a path of incision, thereby ionizing molecules in the tissue lattice thus creating a plasma field as discussed in FDA 510 submission K050933. This was substantiated by proprietary studies under the supervision of Dr Michael Brown, director of the Swarthmore college plasma lab, Swarthmore, PA. It is well know in the electrosurgical literature that all electrosurgical incision units including a Wallach Quantum 500 generate "arcs" which are plasma clouds at the incising tip.

The same electronic system as the Fugo Blade for Dentistry has previously been FDA cleared in FDA 510 K submissions K001498, K041019 and K050933. The Fugo Blade system has also received UL approval and is CSA compliant. The Fugo Blade system complies with ANSI/AAMI HF18:2001, clause 4.2.3.1 for thermal safety. The Fugo Blade system complies with high frequency leakage current requirements specified by ANSI/AAMI HF18:2001, clause 4.2.5.2. These findings support substantial equivalency with the Wallach Quantum 500 system.

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Clinical performance data 807.92(b)(2)

FDA submission K001498 provides statistical significance for safety and efficacy for the Fugo Blade system in the incision/ ablation/ vaporization of highly delicate tissue, namely anterior human lens capsule. Lens capsule is less than 50 microns thick and is extremely fragile tissue. Yet, studies at the University of South Carolina show that the Fugo Blade incision wall of lens capsule had a structural integrity which was un-traumatized and a biomechanical strength characteristic equal to or better than other electrosurgical units. (Appendix #8)

FDA submission 510K K041019 provides statistical significance for safety and efficacy in the incision/ablation/vaporization of extremely dense, strong tissue, namely scleral tissue of the eye. Also, studies at Louisiana State University demonstrated that the Fugo Blade can provide resistance free incisions with minimal trauma to the tissue adjacent to the incision. (Appendix #7)

FDA submission K 050933 provides statistical significance for safety and efficacy for incision/ablation/vaporization with hemostasis in highly vascular tissue, namely the vascular uveal layer of the eye.

These studies support substantial equivalency in clinical performance of the Fugo Blade system to the Wallach Quantum 500 system for Dentistry (FDA 510K K000768) from an intended use perspective (intended use predicate). From a technologic perspective (technologic predicate), the Fugo Blade for Dentistry has been shown to be equivalent to the Fugo Blade for Capsulotomy (FDA 510K K001498), the Fugo Blade for Glaucoma (FDA 510K K041019), and the Fugo Blade for Peripheral Iridotomy (FDA 510K K050933).

#### Summary 807.92(b)(3)

The Fugo Blade for Dentistry is as safe and as effective as the predicate devices. From a technologic perspective (technologic predicate) the Fugo Blade for Dentistry is the same electronic system as FDA cleared systems K001498, K041019, K050933. Therefore, the Fugo Blade for Dentistry has been shown to be equivalent to the technologic predicates.

From an intended use perspective, the Fugo Blade for Dentistry has been shown to be equivalent in terms of safety and effectiveness to the Wallach Quantum 500 system for dentistry (FDA # K000768). These findings are based on preclinical data and clinical data discussed in this application. This data has also previously been described in FDA 510K application K001498, K041019, K050933.

Therefore, the Fugo Blade for Dentistry has been demonstrated to have equivalent safety and efficacy as its technologic predicate and its intended use predicate based on non-clinical and clinical tests.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Richard J. Fugo M.D., Ph.D.  
MediSurg Limited  
100 West Fornance Street  
Norristown, Pennsylvania 19401

APR 18 2007

Re: K063468

Trade/Device Name: The Fugo Blade for Dentistry  
Regulation Number: 21 CFR 872.4920  
Regulation Name: Dental Electrosurgical Unit and Accessories  
Regulatory Class: II  
Product Code: EKZ  
Dated: March 19, 2007  
Received: April 9, 2007

Dear Dr. Fugo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

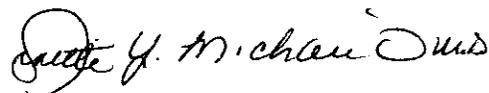
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K063468

## Indications for Use

510(k) Number (if known): K063468

Device Name: The Fugo Blade for Dentistry

### Indications For Use:

- Excisional and incisional biopsy
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Leukoplakia
- Operculectomy
- Gingivoplasty (contouring of gingival tissue)
- Gingivectomy (excision of unsupported gingival tissue)
- Gingival incision and excision
- Hemostatis
- Implant recovery
- Incision and drainage of abscess
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Treatment of aphthous ulcers
- Vestibuloplasty
- Biopsy incision and excision
- Lesion removal
- Tumor removal

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Susan Rinse*

Director  
Division of Anatomic Pathology, General Hospital,  
Regulatory Control, Dental Devices

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510(k) Number   K063468